REMARKS

Applicant acknowledges receipt of the Communication mailed May 4, 2005. There are no outstanding prior art rejections against the claims.

Claims 18 and 29 are amended herein. Claims 27-28 are canceled herein. Claims 1-17 and 31-82 were canceled previously.

Claim 18 has been amended to delete the recitation of "nucleotide analogs and up to 10% base differences," and to recite "SEQ ID NO:74" in place of "SEQ ID NO:73."

Claim 27 has been canceled because the limitation set forth therein is redundant in view of the amendment of Claim 18. Claim 29 has been amended to depend from Claim 21 instead of from canceled Claim 27, which depended from Claim 21.

Claims 18-26 and 29-30 will be pending after entry of the present Amendment.

No new matter is added by the present Amendment.

Entry of this Response is respectfully requested.

The Enablement Rejection Under 35 USC § 112, First Paragraph

Claims 18-30 have been rejected under the enablement requirement of § 112, first paragraph. The Examiner indicated that the Specification, while enabling primer pairs wherein the first primer comprises 22 contiguous bases within SEQ ID NO:74 and the second primer is one from Table 14, does not enable amplification kits comprising primers having the specified

length limitations, but varying from the sequences of SEQ ID NO:74 and SEQ ID NO:59 by inclusion of nucleotide analogs or up to 10% base variation.

The claims have been amended to comply with the enablement requirement of § 112. The amendment of Claim 18 to substitute "SEQ ID NO:74" in place of "SEQ ID NO:73" is supported by the disclosure on page 59 at lines 1-3 which specifically indicates that primers useful for conducting amplification procedures with extraordinary sensitivity were contained within SEQ ID NO:74. Additionally, the primers of SEQ ID Nos:75-77, which are contained within or span the sequence of SEQ ID NO:74, were shown to be useful in combination with primers having sequences contained within the domain defined by SEQ ID NO:59 (*see* Tables 14-15). The amendment of Claim 18 to delete the phrase, "nucleotide analogs and up to 10% base differences" addresses the aspect of the rejection related to sequence variants of the recited first and second primers.

Other language related to the sequence of the "second primer" does not require amendment because this element of Claim 18 is fully enabled by the Specification. The Examiner's statement (*see* Office Action, top of page 5) that the full scope of possible primer sequences from SEQ ID NO:59 is not supported by the Specification focuses only on Table 14 and overlooks the support provided by Table 15. This latter table summarizes results from procedures wherein target-capture and amplification reactions using only 10-20 copies of the WNV nucleic acid target were carried out using a first primer of SEQ ID NO:85 (*i.e.*, the 3' terminal WNV-complementary sequence being SEQ ID NO:76) and either one or two opposite strand primers. The results showed that each of the primers identified by SEQ ID Nos:67-71 advantageously enhanced the sensitivity of an assay that included the primer of SEQ ID NO:64. The final entry in Table 15 shows that SEQ ID NO:68 served as the only opposite strand primer in a reaction that detected the WNV target in 10/10 amplification reactions. Alignment A, presented below, illustrates the relationship of various primer sequences to SEQ ID NO:59, and

shows that the full scope of possible "second primer" sequences is supported by the working Examples, and particularly supported by the results appearing in Tables 14-15.

Alignment A

SEQ ID NO:	
59	TCCGCCACCGGAAGTTGAGTAGACGGTGCTG
60	TCCGCCACCGGAAGTTGAG
62	TCCGCCACCGGAAGTTGAGT
63	TCCGCCACCGGAAGTTGAGTA
64	CGCCACCGGAAGTTGAGT
66	CGCCACCGGAAGTTGAGTA
67	GGAAGTTGAGTAGACGGTGCT
68	GGAAGTTGAGTAGACGGTGCTG
69	GAAGTTGAGTAGACGGTGCT
70	GAAGTTGAGTAGACGGTGCTG
71	AAGTTGAGTAGACGGTGCTG

It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. Moreover, enablement is not precluded by the necessity for some experimentation such as routine screening. (*In re Wands*, 858 F.2d, 8 USPQ2d at 1404; MPEP § 2164.01) In the instant case, the Specification sets forth the sequence of SEQ ID NO:59 from which useful second primers were derived, sets forth length parameters and the minimum number of necessary contiguous bases from SEQ ID NO:59, sets forth screening methods and criteria for identifying useful primers, and sets forth exemplary primers established by these methods. Identifying additional second primers having the recited sequences from within SEQ ID NO:59 represents no more than routine experimentation in the art field related to the design of nucleic acid amplification assays. Accordingly, the Specification enables the claimed pairs of "first" and "second" primers embraced by amended Claim 18, and so the claims should not be limited to primer combinations having only the "second" strand primers recited in Claim 26.

The instant Specification enables the claimed combination of primers from domains within the WNV genome which are disclosed to be particularly useful for conducting highly

sensitive assays. Since Claim 18 has been amended to recite first primers derived from SEQ ID NO:74 instead of from SEQ ID NO:73, since the Specification discloses the use of representative primers derived from SEQ ID NO:74 in combination with representative primers derived from SEQ ID NO:59, and since the recitation of "nucleotide analogs and up to 10% base differences" has been deleted from the claims, Applicant submits that the instantly amended claims are enabled in their full scope. Accordingly, withdrawal of the enablement rejection is appropriate in view of the amendments and explanations presented herein.

The Written Description Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 18-30 have been rejected as failing to comply with the written description requirement under § 112, first paragraph. More specifically, the rejection expresses that the Specification does not reasonably convey that Applicant was in possession of the originally claimed subject matter, which embraced primers having a specified number of contiguous bases from specified primer domains, and that allowed for the presence of nucleotide analogs and up to 10% base variation. The rejection cites MPEP § 2163, which, in relevant part, provides guidance in the examination of claims drawn to a genus, and further cites an excerpt from the Federal Circuit decision rendered in *University of California v. Eli Lilly and Co.*, in support of the rejection.

Applicant traverses the written description rejection by amending the claims, by relying on the disclosure contained in the Specification, and by relying on the Federal Circuit decision cited in the rejection. Claim 18 has been amended to delete the recitation of "nucleotide analogs and up to 10% base differences" which served as a partial basis for the written description rejection, and so obviates this aspect of the rejection. Referring to the Examiner's comment that Table 14 illustrates only a portion of the claimed genus, Applicant points out that supplemental evidence represented in Table 15, which appears to have been overlooked in the examination, also provides support for the instantly claimed genus of "second" primers. With respect to the

generic aspects of both the recited first and second primers, the claim language essentially defines chemical formulae by specifying minimum numbers of contiguous bases contained within polynucleotide sequences limited by SEQ ID Nos. In the case of the claim language covering the structure of the recited first primer, the domain defined by SEQ ID NO:74 is supported by the showing of particularly useful primers identified by SEQ ID Nos:75-77. This arrangement will be clear from reviewing Alignment B, presented below.

Alignment B

SEQ ID:	
74	TCCGAGACGGTTCTGAGGGCTTAC
75	TCCGAGACGGTTCTGAGGGCTTAC
76	TCCGAGACGGTTCTGAGGGCTTA
77	TCCGAGACGGTTCTGAGGGCTT

The claim language essentially sets forth chemical formulae defining the structures of the recited primers. The recitation in Claim 18 of "said 3' terminal target-complementary sequence of said first primer comprising 22 contiguous bases contained within SEQ ID NO:74, allowing for the presence of RNA and DNA equivalents" essentially represents a formula defining generic "first" primers. Likewise, the recitation of "said 3' terminal target-complementary sequence of said second primer comprising 18 contiguous bases contained within SEQ ID NO:59, allowing for the presence of RNA and DNA equivalents" essentially represents a formula defining generic "second" primers. The MPEP section cited in the rejection actually offers alternative criteria that can be used to gauge compliance with the written description requirement, including, "...disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties...." Additionally, the Federal Circuit decision excerpted in the middle of page 7 of the Office Action (*i.e.*, a section that appears to address prosecution of non-original claims), provides guidance for compliance with the written description requirement which is consistent with the path Applicant has followed. Indeed, the court stated:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. (*Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d at 1406 (Fed. Cir. 1997))

In the present case, the relevant language of the original claims, taking the form of formulae defining polynucleotide structures that require contiguous segments from particularly specified sequences, similarly serves as an adequate description of the generically claimed first and second primers.

Since the language of amended Claim 18 defines a genus of first primers and a genus of second primers using formulae reciting contiguous sequences of bases contained within particularly identified larger sequences, and analogous to the chemical arts wherein a formula is normally an adequate description of a claimed genus, and further in light of the deletion of modifying language allowing for the presence of "nucleotide analogs and up to 10% base differences," the amended claims are presented as complying with the written description requirement of § 112. Accordingly, withdrawal of the written description rejection is respectfully requested.

CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by

telephone, the Examiner is invited to contact the undersigned at the telephone number shown below.

Please charge any fees due in connection with this Reply, including the fee for a three-month extension of time, to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to (571) 273-8300 on the date indicated below to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Respectfully submitted,

GEN-PROBE INCORPORATED

Dated: October 28, 2005

By: _____

Michael J. Gilly
Registration No. 42,579
Gen-Probe Incorporated
10210 Genetic Center Drive
San Diego, CA 92121
(858) 410-8657

GP140-04.UT.ROA1.SID_74.wpd